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**From:** Thayer, Kris [thayer.kris@epa.gov]  
**Sent:** 6/28/2021 3:53:54 PM  
**To:** Rodan, Bruce [rodan.bruce@epa.gov]; Lavoie, Emma [Lavoie.Emma@epa.gov]  
**Subject:** FW: Request for Reconsideration (RFR #17002A) Chloroprene Toxicological Review  
**Attachments:** RFR17002A\_02052021.pdf

Some context for my comments on chloroprene and RFC for new data (yellow highlight below).

## Ex. 5 Deliberative Process (DP)

**From:** Noga, Vaughn <Noga.Vaughn@EPA.GOV>  
**Sent:** Friday, February 5, 2021 3:11 PM  
**To:** 'patrick-walsh@denka-pe.com' <patrick-walsh@denka-pe.com>  
**Cc:** Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Gray, David <gray.david@epa.gov>; Wells, Jeffrey <Wells.jeffrey@epa.gov>; Grimm, Patrick <Grimm.Patrick@epa.gov>; Sasser, Erika <Sasser.Erika@epa.gov>; Spina, Providence <Spina.Providence@epa.gov>; Sheppard, Tracy <Sheppard.Tracy@epa.gov>; Chalfant, Katherine <Chalfant.Katherine@epa.gov>; Tallent, Robert <Tallent.Robert@epa.gov>; Alvarado, David <alvarado.david@epa.gov>; Henderson, Austin <Henderson.Austin@epa.gov>  
**Subject:** Request for Reconsideration (RFR #17002A) Chloroprene Toxicological Review

Dear Mr. Walsh,

On July 17, 2019, the U.S. Environmental Protection Agency (EPA) paused the reconsideration of your Information Quality Guidelines (IQGs) request until after the peer review results regarding your submitted PBPK model were fully assessed. This process has now been completed. In accordance with EPA's IQGs, the EPA will now continue the Request for Reconsideration (RFR) process.

The RFR process is described in the EPA Information Quality Guidelines at <https://www.epa.gov/quality/guidelines-ensuring-and-maximizing-quality-objectivity-utility-and-integrity-information>. The addendum dated September 1, 2020 updates position titles for the members of the executive panel in section 8.7 and states; "The executive panel would be comprised of the Science Advisor/AA for the Office of Research and Development (ORD), Chief Information Officer/DAA for OMS-EI, and the Economics Advisor/AA for the Office of Policy (OP)."

The 3-member Executive Panel will be chaired by the Chief Information Officer and Deputy Assistant Administrator for OMS-EI. When the subject of an RFR originates from a member office, that Panel member will be replaced by an alternate Assistant Administrator or Regional Administrator. While the Executive Panel is considering an RFR, the decision made on the initial complaint by the information owner office or region remains in effect. The Executive Panel makes the final decision on the RFR."

Consideration will be given to all information and concerns raised in Denka Performance Elastomer's (DPE's) original RFR submission, the Physiologically Based Pharmacokinetic (PBPK) model that Ramboll has developed, reaction to the peer review report from Denka/Ramboll, and input from the ORD. This information in total will be presented to the Executive Panel for consideration and a decision to accept or reject your request will be rendered.

There comes a time in the process when the EPA must take the information it has and proceed with the RFR process and we have reached that point. The purpose of the RFR process is to have an independent, objective review by the Executive Panel of all the pertinent information. Consequently, the work to be done is now internal to the EPA. It would

be inappropriate for anyone from EPA to hold further discussions with you or anyone from your company or anyone representing it until the Executive Panel has met and made its decision and the Agency has informed you of it in writing.

Alternatively, DPE may withdraw this RFR prior to the Executive Panel meeting and submit a new Request for Correction. If you wish to withdraw the RFR, please inform Katherine Chalfant here at EPA in writing. EPA plans to convene the Executive Panel in March 2021. Therefore, if you plan to withdraw this RFR, we recommend you inform EPA in writing no later than March 1, 2021.

Know that we appreciate your position. There has been a voluminous amount of information gathered relevant to this RFR with many resources and hours contributed by all concerned. We at the EPA take very seriously our duty to reach carefully considered, scientifically justified decisions in these matters.

Sincerely,

Vaughn Noga, Chief Information Officer  
and Deputy Assistant Administrator for Environmental Information  
Office of Mission Support  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave  
Washington DC 20460